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EXAMINER	
CROW, ROBERT THOMAS	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,786	OLDHAM ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,88-93 and 95-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19, 88-93, and 95-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4 June 2008 and the supplemental submission filed 12 September 2008 have each been entered.

Status of the Claims

2. This action is in response to Applicant's submission filed on 4 June 2008 and the supplemental submission filed 12 September 2008 in which claim 91 was amended, claims 61-80 and 94 were canceled, and new claims 95-98 were added. All of the amendments have been thoroughly reviewed and entered.

The interview summary is acknowledged and the interview record is complete.

The previous rejections under 35 U.S.C. 112, first paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 16-19, 88-93, and 95-98 are under prosecution.

3. The following are new objections and rejections necessitated by the amendments.

Claim Objections

4. Claims 88-90 are objected to because of the following informalities: each of claims 88-90 depends upon claim 94, which has been cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 88-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 88-90 depends upon claim 94, which has been cancelled; thus, it is unclear what claim each of claims 88-90 is dependent upon.

7. For the purpose of examination, claims 88-90 are each interpreted as being dependent upon independent claim 91.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 91, 16-19, 88-90, 92, 93, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakobsen et al (PCT International Publication No. WO 02/097398 A2, published 5 December 2002) in view of Sobek (U.S. Patent Application Publication No. US 2005/0098750 A1, filed 6 November 2003), or, alternatively further in view of Rius et al (U.S. Patent No. 6,539,651 B1, issued 1 April 2003), and, as applied to claim 89, as evidenced by the online dictionary at dictionary.caimbridge.org, and, as applied to claim 98, as evidenced by Fouillet et al (U.S. Patent Application US 2001/0041357 A1, published 15 November 2001) and Goh et al (U.S. Patent Application Publication No. US 2002/0025534 A1, published 28 February 2002).

Regarding claim 91, Jakobsen et al teach a microfluidic device. In a single exemplary embodiment, Jakobsen et al teach a microfluidic device comprising a sample distribution network in the form of channels formed in a substrate (Figure 9 and pages 39-40). The distribution network is used for PCR processing of nucleic acids (page 13, lines 15-25), and comprises a sample containment region in the form of analysis area 212, a sample inlet region in the form of inlet port 214a, and a sample outlet region in the form of sample outlet 320 (pages 39-40 and Figure 9). The device further comprises a first cover layer sealing the sample distribution network; namely, the device is a closed substrate (Title and Abstract) having a plastic polyolefin cover clip which covers the inlet ports (page 41, line 25-page 42, line 15 and page 11, line 22-page 12, line 3), thereby sealing them (page 4, lines 12-24). Instant claim 89 requires the gas-impermeable first cover layer to be a polyolefin; thus, the polyolefin cover of Jakobsen et al is a gas-impermeable material in accordance with the requirements of instant claim

89. In addition, the instant specification offers no guidance as to what materials are encompassed by the term a "gas-impermeable material." Thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "gas-impermeable material" (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1]).

Jakobsen et al further teach the device comprises a venting region formed in fluid communication with the outlet region; namely, vent 402, which has a second cover in the form of a cap that is an air (i.e., gas) permeable seal (page 39, lines 5-11). Vent 402 is positioned away from sample containment region 212 (Figure 9), and is in fluidic communication with the sample outlet region because the vent is connected to a waste area (page 4, lines 5-11), which, in turn, is connected to the outlet port (page 39, lines 11-22).

It is noted that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories,* 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown

to be less than optimal does not vitiate the fact that it is disclosed."). Thus, the teaching of Jakobsen et al that the cover **may** cover all vents encompasses the alternate embodiment wherein the cover does **not** cover the air vent. See MPEP § 2123 [R-5].

While Jakobsen et al teach the device comprises a vent for expulsion of air from the sealed container (page 20, lines 20-23), Jakobsen et al do not teach the seal for the vent comprises a non-porous, gas permeable second cover layer and a third cover layer formed from a gas-impermeable material applied to the second cover layer.

However, Sobek teaches an electrostatic seal 310 for use in a microfluidic device (Figure 2D and paragraphs 0031-0038). The seal comprises a first electrode 104 in the channel being sealed, as well as elastic layer 106 and electrode layer 102, which are the claimed second and third cover layers as described below and are removable from the substrate (paragraph 0031). Sobek teaches the elastic layer (i.e., the claimed second cover layer) 106 is polydimethylsiloxane (paragraph 0041), which is a non-porous, gas-permeable material in accordance with paragraph 00041 of the instant specification. Sobek further teaches the electrode layer (i.e., the claimed third cover layer) is made of aluminum (paragraph 0039), which is a preferred material for the gas-impermeable layer in accordance with paragraph 00035 of the instant specification. Sobek also teaches the multilayer seal has the added advantage of reducing possible interference with optical interrogation of the microfluidic structure (Abstract). Thus, Sobek teaches the known technique of using a non-porous, gas permeable second cover layer and a third cover layer applied to the second cover layer.

It is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 91 (e.g., use of the third cover layer to prevent evaporation from the at least one sample containment region) fail to define additional structural elements of the claimed device. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art. See MPEP § 2114.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the microfluidic device comprising a sealed vent on the substrate as taught by Jakobsen et al so that the seal on the venting region is an electrostatic seal comprising a non-porous, gas permeable second cover layer and a third cover layer applied to the second cover layer as taught by Sobek to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a seal that has the added advantage of reducing possible interference with optical interrogation of the microfluidic structure as explicitly taught by Sobek (Abstract). In addition, it would have been obvious to the ordinary artisan that the known technique of using the electrostatic

seal comprising a non-porous, gas permeable second cover layer and a third cover layer applied to the second cover layer as taught by Sobek could have been applied as the seal on the venting region of the device of Jakobsen et al with predictable results because the known technique of using the electrostatic seal comprising a non-porous, gas permeable second cover layer and a third cover layer applied to the second cover layer as taught by Sobek predictably results in a reliable seal for use in a microfluidic device.

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594, because Sobek is silent with regard to an aluminum electrode that is gas-impermeable. However, the gas-impermeable nature of the aluminum electrode is deemed to be inherent in the prior art of Sobek because Sobek teaches the gaps that are sealed by the cover layers are filled with air (paragraph 0021). Because the gap is sealed and has air sealed therein, the overall structure must be gas-impermeable, or else the air would escape. Because the elastic layer is polydimethylsiloxane, which is gas permeable, the electrode layer must be gas impermeable in order to maintain the airtight seal. The burden is on Applicant to show that the claimed gas-impermeability is either different or non-obvious over that of Sobek.

Alternatively, Rius et al teach impermeable aluminum is a good material because it is impermeable to liquid and steam (which is a gas), is resistant to high temperatures, is easily punched and formed, and has good wear resistance (column 3, lines 15-30). Thus, Rius et al teach the known technique of using impermeable aluminum.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the microfluidic device comprising the aluminum electrode as taught by Jakobsen et al in view of Sobek so that the aluminum is gas-impermeable aluminum as taught by Rius et al to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a electrode having the added advantage of being impermeable to liquid and steam (which is a gas), is resistant to high temperatures, is easily punched and formed, and has good wear resistance as explicitly taught by Rius et al (column 3, lines 15-30). In addition, it would have been obvious to the ordinary artisan that the known technique of using the gas-impermeable aluminum as taught by Rius et al could have been applied as the seal on the venting region of the device of Jakobsen et al in view of Sobek with predictable results because the known technique of using the gas-impermeable aluminum as taught by Rius et al predictably results in a material that has excellent mechanical properties.

Regarding claims 16-18, the device of claim 91 is discussed above. Jakobsen et al teach the sample containment region further comprises a dried nucleic acid sequence probe; namely, a spotted array of nucleic acids is disposed in the sample containment region (i.e., claim 17), wherein the array is dried (i.e., claims 16 and 18; page 71).

Regarding claim 19, Jakobsen et al teach the device of claim 91, wherein the sample containment region comprises a plurality of sample containment regions in an array; namely, the device comprises a plurality of analysis areas (page 15, lines 10-20),

which are sample containment areas. The "plurality" of Jakobsen et al encompasses two sample containment regions, which are in a linear array because two points (i.e., regions) are always in a straight line, and art thus linearly arrayed.

Regarding claims 88-90, the device of claim 91 is discussed above.

Jakobsen et al do not teach the gas-impermeable first cover layer comprises an aluminum film (i.e., claim 88) or a polyolefin film (i.e., claim 89) of the polyolefin material polytetrafluoroethylene (i.e., claim 90).

However, Sobek teaches an electrostatic seal 310 for use in a microfluidic device (Figure 2D and paragraphs 0031-0038). The seal comprises a first electrode 104 in the channel being sealed, as well as elastic layer 106 and electrode layer 102, which is collectively interpreted as the claimed first gas-impermeable cover layer and is removable from the substrate (paragraph 0031). Sobek teaches the elastic layer (i.e., second cover) layer 106 is polytetrafluoroethylene (paragraph 0041), which is a polyolefin layer because it is derived from the olefin polyfluoroethylene. A review of the specification yields no limiting definition of a "film." Thus, the thin layer of polytetrafluoroethylene is a polyolefin film layer (i.e., claim 89) in accordance with the definition of a "film" as "a thin layer of something on a surface" provided by the online dictionary at dictionary.caimbridge.org, and the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "polyolefin film." Sobek further teaches the electrode portion of the layer is made of aluminum (paragraph 0039), which is a preferred material for the gas-impermeable layer in accordance with paragraph 00035 of the instant specification. Sobek also

teaches the multilayer seal has the added advantage of reducing possible interference with optical interrogation of the microfluidic structure (Abstract). Thus, Sobek teaches the known technique of using a non-porous, gas permeable cover layer.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the microfluidic device comprising the first cover layer as taught by Jakobsen et al so that the sealing first cover layer is the electrostatic of Sobek, which comprises both an aluminum film layer (i.e., claim 88) and a layer of the polyolefin (i.e., claim 89) polytetrafluoroethylene (i.e., claim 90), to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a seal that has the added advantage of reducing possible interference with optical interrogation of the microfluidic structure as explicitly taught by Sobek (Abstract). In addition, it would have been obvious to the ordinary artisan that the known technique of using the electrostatic seal as taught by Sobek could have been applied as the first sealing cover layer on the device of Jakobsen et al with predictable results because the known technique of using the electrostatic seal as taught by Sobek predictably results in a reliable seal for use in a microfluidic device.

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594, because Sobek is silent with regard to an aluminum electrode that is gas-impermeable. However, the gas-impermeable nature of the aluminum electrode is deemed to be inherent in the prior art of Sobek because Sobek teaches the gaps that

are sealed by the cover layers are filled with air (paragraph 0021). Because the gap is sealed and has air sealed therein, the overall structure must be gas-impermeable, or else the air would escape. Because the elastic layer is polydimethylsiloxane, which is gas permeable, the electrode layer must be gas impermeable in order to maintain the airtight seal. The burden is on Applicant to show that the claimed gas-impermeability is either different or non-obvious over that of Sobek.

Alternatively, Rius et al teach impermeable aluminum is a good material because it is impermeable to liquid and steam (which is a gas), is resistant to high temperatures, is easily punched and formed, and has good wear resistance (column 3, lines 15-30). Thus, Rius et al teach the known technique of using impermeable aluminum.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the microfluidic device comprising the aluminum electrode as taught by Jakobsen et al in view of Sobek so that the aluminum is gas-impermeable aluminum as taught by Rius et al to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a electrode having the added advantage of being impermeable to liquid and steam (which is a gas), is resistant to high temperatures, is easily punched and formed, and has good wear resistance as explicitly taught by Rius et al (column 3, lines 15-30). In addition, it would have been obvious to the ordinary artisan that the known technique of using the gas-impermeable aluminum as taught by Rius et al could have been applied as the seal on the venting region of the device of

Jakobsen et al in view of Sobek with predictable results because the known technique of using the gas-impermeable aluminum as taught by Rius et al predictably results in a material that has excellent mechanical properties.

Regarding claim 92, Jakobsen et al teach the device of claim 91, wherein the substrate is glass or a polymer material (i.e., plastic; page 11, line 15-page 12, line 3), and can withstand thermal cycling between 60 °C and 95 °C (page 13, lines 15-25).

Regarding claim 93, the device of claim 91 is discussed. Sobek teaches the elastic layer (i.e., second cover layer) 106 is polydimethylsiloxane (paragraph 0041), which is a non-porous, gas-permeable material in accordance with paragraph 00041 of the instant specification. Thus, modification of the device of Jakobsen et al with the teachings of Sobek results in a deice having a non-porous, gas-permeable second made of a polysiloxane material.

Regarding claim 98, the device of claim 91 is discussed above.

While Jakobsen et al teach the use of a sealing septum made of an elastomer (page 30, lines 1-10) and that the device is used for PCR (page 13, lines 15-25), Jakobsen et al do not explicitly teach the first cover layer comprises an elastomeric material adapted for use with PCR.

However, Sobek teaches an electrostatic seal 310 for use in a microfluidic device (Figure 2D and paragraphs 0031-0038). The seal comprises a first electrode 104 in the channel being sealed, as well as elastic layer 106 and electrode layer 102, which is collectively interpreted as the claimed first gas-impermeable cover layer and is removable from the substrate (paragraph 0031). Sobek teaches the elastic layer 106 is

polydimethylsiloxane (paragraph 0041), which is an elastomeric material adapted for use with PCR as evidenced by Fouillet et al, who teach that microfluidic substrates me of polydimethylsiloxane (paragraph 0045) are used for PCR reactions (paragraph 0321), and as evidenced by Goh et al, who teach that polydimethylsiloxane is an elastomer (paragraph 0076). Sobek further teaches the electrode layer (i.e., the claimed third cover layer) is made of aluminum paragraph 0039), which is a preferred material for the gas-impermeable layer in accordance with paragraph 00035 of the instant specification. Sobek also teaches the multilayer seal has the added advantage of reducing possible interference with optical interrogation of the microfluidic structure (Abstract). Thus, Sobek teaches the known technique of using a seal comprising an elastomeric material adapted for use with PCR.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the microfluidic device comprising the first cover layer as taught by Jakobsen et al so that the sealing first cover layer is the electrostatic seal of Sobek, which comprises a layer of an elastomeric material adapted for use with PCR in the form of polydimethylsiloxane, to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having a seal that has the added advantage of reducing possible interference with optical interrogation of the microfluidic structure as explicitly taught by Sobek (Abstract). In addition, it would have been obvious to the ordinary artisan that the known technique of using the electrostatic seal as taught by Sobek

could have been applied as the first sealing cover layer on the device of Jakobsen et al with predictable results because the known technique of using the electrostatic seal as taught by Sobek predictably results in a reliable seal for use in a microfluidic device.

11. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jakobsen et al (PCT International Publication No. WO 02/097398 A2, published 5 December 2002) in view of Sobek (U.S. Patent Application Publication No. US 2005/0098750 A1, filed 6 November 2003), or, alternatively further in view of Rius et al (U.S. Patent No. 6,539,651 B1, issued 1 April 2003), as applied to claim 91 above, and further in view of Farahmandi et al (U.S. Patent No. 6,233,135 B1, issued 15 May 2001).

Regarding claim 95, the device of claim 91 is discussed above in Section 10.

Sobek teaches third cover layer (i.e., electrode layer) 103 of Sobek is made of aluminum (paragraph 0039), and is a film (claim 5 of Sobek). Thus, modification of the device of Jakobsen et al so that the third seal on the venting region is the electrostatic seal of Sobek results in a seal having a gas-impermeable aluminum electrode film layer.

Alternatively, modification of the device of Jakobsen et al in view of Sobek with the teachings of Rius et al results in a seal having a gas-impermeable aluminum electrode film layer.

While Sobek teaches the area sealed by the aluminum film layer is airtight (paragraph 0021), and while Rius et al also teaches the aluminum forms an airtight seal

(column 3, lines 15-30), neither Jakobsen et al, Sobek, or Rius et al explicitly teach the aluminum film layer forming the air-tight seal is non-porous aluminum.

However, Farahmandi et al teach a preferred embodiment of electrodes wherein the electrodes are made of non-porous aluminum (column 9, lines 38-45). Thus, Farahmandi et al teach the known preferred technique of using non-porous aluminum for making electrodes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device comprising a gas impermeable electrode (i.e., third cover) layer as taught by Jakobsen et al in view of Sobek and Rius et al so that the electrode is made of non-porous aluminum as taught by Farahmandi et al to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because Sobek teaches airtight sealing via the electrode (i.e., third cover) layer, and the sealing would be aided by use of the non-porous aluminum electrode as taught by Farahmandi et al. In addition, it would have been obvious to the ordinary artisan that the known technique of using the non-porous aluminum electrode as taught by Farahmandi et al could have been applied as the aluminum electrode in the device of Jakobsen et al in view of Sobek and Rius et al with predictable results because the known technique of using the non-porous aluminum electrode as taught by Farahmandi et al predictably results in a viable electrode.

12. Claims 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakobsen et al (PCT International Publication No. WO 02/097398 A2, published 5 December 2002) in view of Sobek (U.S. Patent Application Publication No. US 2005/0098750 A1, filed 6 November 2003), or, alternatively further in view of Rius et al (U.S. Patent No. 6,539,651 B1, issued 1 April 2003), as applied to claim 91 above, and further in view of Ouellet et al (U.S. Patent Application Publication No. US 2002/0160561 A1, published 31 October 2002).

Regarding claims 96-97, the device of claim 91 is discussed above in Section 10.

Figure 2D of Sobek teaches the claimed second and third cover layers; namely, the second cover layer is elastic layer 106, and the third cover layer is interpreted as both the electrode layer 102 and the remainder of the substrate 108 on top of electrode 102.

Neither Jakobsen et al, Sobek, nor Rius et al explicitly teach a substrate comprising a layer made of polytetrafluoroethylene (i.e., claim 97), which is a polyolefin film (i.e., claim 96) because ethylene is an olefin.

However, Ouellet et al teach the use of polytetrafluoroethylene substrates (paragraph 0056) in microfluidic devices (Abstract). Ouellet et al also teach polytetrafluoroethylene films (paragraph 0060). Ouellet et al further teach polytetrafluoroethylene substrates have the added advantage of being readily bound to other substrates and being readily patterned by microstamping and lithography (paragraph 0056). Thus, Ouellet et al teach the known technique of using the polyolefin polytetrafluoroethylene as a substrate material and as a film.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the device comprising the gas-impermeable third cover layer made up of a gas-impermeable aluminum electrode and a substrate and as taught by Jakobsen et al in view of Sobek and Rius et al so that the substrate is a polyolefin film layer (i.e., claim 96) made of polytetrafluoroethylene (i.e., claim 97) to arrive at the instantly claimed device with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a device having the added advantage of being readily bound to other substrates and being readily patterned by microstamping and lithography as explicitly taught by Ouellet et al (paragraph 0056). In addition, it would have been obvious to the ordinary artisan that the known technique of having a substrate that is a polyolefin film layer (i.e., claim 96) made of polytetrafluoroethylene (i.e., claim 97) as taught by Ouellet et al could have been applied to as the upper substrate on the third cover layer of the device of Jakobsen et al in view of Sobek and Rius et al with predictable results because the known technique of having a substrate that is a polyolefin film layer (i.e., claim 96) made of polytetrafluoroethylene (i.e., claim 97) as taught by Ouellet et al predictably result in the use of a substrate compatible with microfluidic devices.

Response to Arguments

13. Applicant's arguments filed 4 June 2008 (hereafter the "Remarks") and 12 September 2008 (hereafter the "Supplemental Remarks") have been fully considered but they are not persuasive for the reasons listed below.

A. It is noted that the Supplemental Remarks in clued the following:

I. A summary of the interview of 4 June 2008. As noted above, the interview record is complete.

II. A reiteration of the citations of support for the amendments, which are also stated in the Remarks considered below.

III. A reiteration of the arguments regarding back pressure that are also found in the Remarks.

Because the arguments presented in the Supplemental Remarks are considered below, the response to the Supplemental Arguments is complete.

B. Applicant's arguments on pages 7-8 of the Remarks regarding to the previous rejections of the claims as anticipated by Jakobsen et al are moot in view of the new ground(s) of rejection necessitated by the amendments.

C. Applicant argues on pages 8-9 of the Remarks that Jakobsen et al teach that vent 402 may be constructed of any porous polymer film (page 39 of Jakobsen et al), and thus does not describe using a non-porous, gas permeable material as required by the claim.

However, as noted above, that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including

nonpreferred embodiments. Thus, the teaching of Jakobsen et al that the vent is sealed "preferably" with a hydrophobic, air permeable material encompasses the alternate embodiment wherein the "structure [that] will allow for escape of air while, maintaining fluid in the device" recited on page 39 of Jakobsen is **not** a hydrophobic, air permeable material; namely, the removable seals of Sobek in view of Rius et al as described above.

D. Applicant's arguments on page 9 of the Remarks regarding Paradine have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

E. Applicant argues on pages 9-10 of the Remarks that the addition of a gas-impermeable cover layer to the vent of Jakobsen et al would prohibit the expulsion of air from the device upon addition of fluid to the device.

However, as noted above, Jakobsen et al specifically teaches that vent 402 and be covered, e.g., with which a second cover in the form of a cap that is an air (i.e., gas) permeable seal (page 39, lines 5-11).

Furthermore, Jakobsen et al also teach the device comprises two air vents (402 and 406; page 40). Thus, the sealing of one vent does not prevent to removal of back-pressure through the other vent.

In addition, MPEP 716.01(c) makes clear that "[t]he arguments of counsel cannot take the place of evidence in the record" (*In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)). Thus, the arguments a cover layer on the vent prevents fluid

from moving throughout the closed substrate cannot take the place of evidence in the record.

F. Applicant's remaining arguments on pages 10-11 of the Remarks with respect to the previous rejections of the claims are moot in view of the new ground(s) of rejection necessitated by the amendments.

Conclusion

14. No claim is allowed

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Robert T. Crow/
Examiner, Art Unit 1634

Robert T. Crow
Examiner
Art Unit 1634